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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,953	02/12/2004	Scott Cordray	3091-0	5981

7590                    02/13/2008  
JOHN LEZDEY AND ASSOCIATES  
SUITE 118  
2401 WEST BAY DRIVE  
LARGO, FL 33770

EXAMINER
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CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

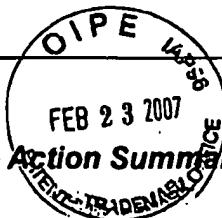
MAIL DATE	DELIVERY MODE
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02/13/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



 <b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/018,953	CORDRAY, SCOTT	
<b>Examiner</b> Frank I. Choi	<b>Art Unit</b>		
	1616		

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

#### ANSWER

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on \_\_\_\_.

2a)  This action is **FINAL**.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-35 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) 1-35 is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 20020411.

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .

5)  Notice of Informal Patent Application

6)  Other: \_\_\_\_ .

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,2 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 60164467 A2.

JP 60164467 A2 expressly discloses a sterile composition comprising Dead Sea salts and water (Abstract)..

Claims 7,8 are rejected under 35 U.S.C. 102(a) as being anticipated by EP 0 937 453 A2.

EP 0 937 453 A2 expressly discloses a sterile composition containing Dead Sea salts (Pg. 3, lines 26-39, Pg. 5, lines 43-60, Pgs. 6-7, Pg. 8, lines 1-15).

Claims 3-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 937 453 A2 in view of Gennaro.

EP 0 937 453 A2 discloses a nasal spray formulation composition containing Dead Sea salts for treatment of nasal or sinus congestion and to soothe coughing irritations due to bronchitis or similar conditions (Pg. 3, lines 26-39, Pg. 5, lines 43-60, Pgs. 6-7, Pg. 8, lines 1-15, 34, 24).

Gennaro discloses that pharmaceutical preparations are typically sterile, nasal solutions are typically aqueous, isotonic and slightly buffered to maintain a pH of 5.5 to 6.5 and, optionally, contain preservatives and stabilizers, and various aerosol preparations and devices, including methods of producing aerosol in situ (Pgs. 1293, 1500, 1662-1677).

The difference between the prior art and the claimed invention is that the prior art does not explicitly disclose a nasal spray formulation comprising a Dead Sea salt and mineral composition which contains a buffer or is present in the amount of 0.5 to about 5 grams per liter of solution, or a method of treating using a or a method of making a nasal spray containing Dead Sea Salts. However, the prior art amply suggests the same as method of using and method of preparing nasal sprays are well known in the art and it is known to prepare an use a nasal spray containing Dead Sea salts for the treatment of congestion and bronchitis and similar conditions. As such it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation of formulating a nasal spray which is effective in obviate the effect of modern environmental conditions on the human body (EP 0 937 453 A2, Pg. 2, lines 24-31).

It is noted that this PCT case claims priority to U.S. Application Serial No. 09/345,043, filed 6/30/99. However, that U.S. Application does not appear to disclose a buffer, pH, amount in grams per liter of aqueous solution, that the product is essentially free of noxious organic impurities, the specific concentration of salts and minerals, a method of treating symptoms of adverse conditions affecting the nasal cavity and passageway comprising the steps of identifying patient with an adverse nasal cavity condition, obtaining a premixed formulation containing a Dead Sea salt and mineral composition in aqueous solution; and administering an aerosol formed from the formulation at least 1 time a day as symptoms of the patient persist, a

Art Unit: 1616

method of treating symptoms of adverse conditions affecting the nasal cavity and passageway with a Dead Sea salt and mineral composition in aqueous solution, comprising the steps of obtaining a premixed formulation containing a Dead Sea salt and mineral composition in aqueous solution; and self-administering an aerosol formed from said formulations nasally at least 1 time a day as symptoms persist, or a method of producing a nasal spray formulation comprising Dead Sea salt in aqueous solution comprising dissolving Dead Sea salt in aqueous solution and storing this premixed formulation in a container suitable for aerosol nasal administration. As such, although EP 0 937 453 A2 was published after the priority date but before the international filing date, its disclosure is still prior art as to Claims 3-35.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

#### *Conclusion*

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Dr. Johann Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi  
Patent Examiner  
Technology Center 1600  
January 7, 2007



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER